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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,333	08/20/2003	Bernd Disse	01-1196-1-C1	6665
28519 7590 09/29/2009 MICHAEL P. MORRIS BOEHRINGER INGELHEIM USA CORPORATION 900 RIDGEBURY RD P O BOX 368 RIDGEFIELD, CT 06877-0368				
EXAMINER SAMALA, JAGADISHWAR RAO				
ART UNIT 1618		PAPER NUMBER		
NOTIFICATION DATE 09/29/2009		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/644,333

**Applicant(s)**

DISSE, BERND

**Examiner**

JAGADISHWAR R. SAMALA

**Art Unit**

1618

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 11 August 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 09/11/2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala  
Examiner  
Art Unit: 1618

Continuation of 11, does NOT place the application in condition for allowance because: Contrary to applicant assertion that O'Byrne reference has brought as new reference and therefore the rejection is, in essence, a new ground of rejection. This assertion is found not persuasive for the following reasons; Applicant rebuttal that COPD dose not encompasses treatment of cystic fibrosis necessitated the evidence by O'Byrne which is solely used to show that COPD encompasses cystic fibrosis. Specifically as taught by O'Byrne (page S47), it known in the art that small airway disease involve an appearance and increase in number of goblet cells, an increase in the amount of mucus in the lumen, the presence of inflammation, an increase in muscle mass in the walls of the bronchioles, and, ultimately, fibrosis. The diseases of cystic fibrosis and COPD are characterized by mucus-congested airways. Agents that stimulate the secretion of Cl- are anticipated to facilitate mucociliary clearance and thus be of benefit in the treatment of cystic fibrosis and COPD. Thus, this is not a new grounds of rejection, rather a reference to support an inherent feature in the original rejection. Note, this reference was only cited as an "evidenced by" citation.

Applicant asserts that Maesen does not teach that tiotropium bromide can be used to treat any specific symptom of COPD-whether associated with COPD or not. This argument is not persuasive because, Maesen teaches that inhaled tiotropium bromide induced bronchodilation in COPD patients. Since COPD encompasses the cystic fibrosis, it would inherently treat cystic fibrosis. Applicant further asserts that Skupin does not teach or suggests a method for treating a disease selected from cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis, the combination of references cannot teach or suggest this element of the claimed invention. This argument is not persuasive because Skupin reference is relied upon for their teachings the use of certain excipients in the treatment of COPD which includes such entities as cystic fibrosis, chronic bronchitis, emphysema, and COPD where it is associated with asthma.

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